REMARKS

This is responsive to the Office Action mailed on December 19, 2006. In the Office Action, claims 1-9, 11-28, and 34-43 were rejected. Claim 44 has been added. Support for claim 44 can be found on at least page 18, lines 15-17 of the application. The Application currently includes claims 1-9, 11-28, and 34-44. Reconsideration of the claims is requested.

The Office Action rejected claims 1-9, 11-28, and 34-43 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action alleges that the claims contain subject matter which was not described in the specification in a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action alleges that there is no support in the specification for reciting the claim limitation "the bridges are not glutaraldehyde" in claims 1 and 16, and "the bridge molecules are not glutaraldehyde" in claims 34, and 36.

Applicants respectfully disagree that claims 1, 16, 34, and 36 do not comply with the written description requirement under 35 U.S.C. § 112, first paragraph. However, to further prosecution, claim 44 has been added to recite the Markush group of the specific bridge compounds, as suggested by the Examiner.

Applicant is claiming a negative limitation in claims 1, 16, 34, and 36. Negative limitations are proper. *See* MPEP 2173.05 (i). At page 6, lines 9-13, the specification states that bridges are chemically different from linkers, and the functional groups of the bridges are generally non-reactive with unmodified tissue or with other bridges. Linkers are defined in the application at page 12, line 14-page 17, line 4. At page 13, lines 8-9 of the application, linkers are disclosed to include crosslinking agents. Referring to page 13, lines 16-20 of the application, dialdehyde crosslinking agents include glutaraldehyde.

In contrast to a linker, bridges include two or more functional groups that react with the linkers. The bridges include functional groups having methylthio groups, thio groups, amine groups, alcohol groups and carboxyl groups. Page 18, lines 11-19. There is no disclosure of a

bridge having two aldehyde groups.

Therefore, Applicants were in possession of the subject matter including that linkers and bridges are chemically different. Having the knowledge that glutaraldehyde is a linker and linkers are different from bridges, and that bridges do not include aldehyde groups, Applicants can properly negatively claim that a bridge is not glutaraldehyde while complying with 35 U.S.C. §112, first paragraph.

See generally MPEP 2173.05(i) that discloses that any negative limitation or exclusory proviso must have a basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. *See in re Johnson* 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification having described the whole, necessarily described the part remaining."). *See also Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). Therefore, Applicants respectfully request that the 35 U.S.C. § 112, first paragraph, rejections be withdrawn.

The Office Action rejected claims 1-9, 11-28, and 34-43 under 35 U.S.C. §103(a) as being unpatentable over the Ogle et al. U.S. Pat. No. 5,958,669 in view of the Yang et al. U.S. Pat. No. 5,935,168. The Office Action alleges that the Ogle patent discloses crosslinking tissue to fix tissue by reacting the tissue with glutaraldehyde. The Office Action alleges that the Yang patent discloses crosslinking tissue with glutaraldehyde and then reacting with a diamine followed by reacting with additional glutaraldehyde. The Office Action alleges that after reacting with glutaraldehyde, as disclosed by the Ogle patent, it would have been obvious to react with diamine and then with additional glutaraldehyde as suggested by the Yang patent. The Office Action alleges that this would result in the diamine being a linker and glutaraldehyde being a bridge. Additionally, after initially crosslinking with glutaraldehyde some free aldehyde groups will remain that will react with the diamine and will result with the glutaraldehyde being a linker and the diamine being a bridge. The Office Action alleges that the aldehyde groups of glutaraldehyde are generally non-reactive with other aldehyde groups of another glutaraldehyde under certain conditions disclosed in the Ogle Patent that controls self-polymerizing. The Office Action alleges that the amine group of a diamine will not react with amine groups of another

diamine, and that this results in a bridge not reacting with another bridge.

Applicants respectfully disagree that any of the rejected claims are made obvious by the combination of the Ogle Patent and the Yang Patent. There is no teaching or suggestion which would lead one to combine the Ogle Patent with the Yang Patent except for the present invention.

The Office Action alleges that both the Ogle Patent and the Yang Patent are directed to preventing calcification of a prosthesis. In contrast, the present invention is directed to a novel crosslinked tissue and methods of making a crosslinked tissue having strength and flexibility. Two patents directed to preventing calcification of a prosthesis does not provide the motivation to allege that a novel crosslinked tissue is obvious. Again, it is not understood how the Office Action properly made the combination of the Ogle Patent with the Yang Patent, absent using the present invention as a guide.

Further, the Office Action has failed to provide any factual support for the allegation that when free aldehyde groups are present, a diamine will react with both activated carboxyl groups or the free aldehyde groups. Applicants submit that, as an example, there may be steric hindrance which would prevent the free aldehyde groups and carboxyl groups from reacting. The Office Action has failed to prove a case of *prima facie* obviousness. As such, claims 1-9, 11-28, and 34-43 are not made obvious by the combination of the Ogle Patent with the Yang Patent.

Further, Applicants claim that the linkers be bonded to the tissue. The Office Action alleges that utilizing a second treatment of glutaraldehyde after treating cross-linked tissue with diamine meets the claim limitations. However, there is no teaching that the second treatment with glutaraldehyde both bonds to the amine functional group and also the tissue as claimed. Also, there is no disclosure in the Yang patent that both diamines bond to the linkers attached to the tissue as claimed. Otherwise, there would be no requirement for the second treatment with glutaraldehyde.

Applicants also incorporate by reference the remarks made in its Response in its March 24, 2006 submission.

Therefore, for the foregoing reasons, none of the claims of the present invention are

made obvious by the Ogle Patent in view of the Yang Patent. Reconsideration and allowance of claims 1-9, 11-28, and 34-44 are respectfully requested.

Applicant has previously paid for six independent claims and 38 claims, so no additional claim fees should be required. However, the Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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